Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the effect of intranasal ketamin and intranasal dexmedetomedin versus placebo on sedation,bleeding,pain & agitation in children undergoing adenotonsilectomy

Protocol summary

Study aim
Effects of intranasal ketamine and dexmedetomidine versus placebo on preoperative pediatric rest, intraoperative bleeding, restlessness and pain in patients undergoing adenotonsillectomy

Design
A randomized, triple-blind, placebo-controlled clinical trial

Settings and conduct
In this study, children in need of elective adenotonsillectomy surgery were recruited at Besat Hospital in Hamedan in 1979. Patients were randomly divided into three groups of dexmedetomidine (D), ketamine (k) and placebo control (normal saline). (NS) are segmented. Patients were given 2 mg / kg dexmodetimidine or 5 mg / kg ketamine 30 minutes prior to induction of anesthesia and in the control group received 5 drops of 9% normal saline with 2 mg syringe when the child was present with their parents. Be. Medications are poured into both nostrils. Blood pressure, pulse rate, and Spo2 are measured every 15 minutes after the drug is administered until the patient leaves the recovery room.

Participants/Inclusion and exclusion criteria
Children 4 to 12 years old undergoing adenotonsillectomy surgery • Inclusion criteria 1. Age 4 to 12 years 2. Candidate for tonsillectomy 3. Patient class according to American Society of Anesthesiology (ASA) ratings one and two • Exclusion criteria 1. Drug sensitivity to ketamine or dexmedothymidine 2. Mental retardation 3. Hyperactivity 4. Psychiatric drug use 5. History of heart, kidney, liver disease 6. Any pathological problems in the nose 7. Patients returning to the operating room due to postoperative bleeding

Intervention groups
• Intervention group 1: Intranasal ketamine 5 mg / kg • Intervention group 2: Intranasal dexmedothymidine 2 µg / kg • Comparison Group: Normal intranasal saline 2 cc

Main outcome variables
Assessment of relaxation before anesthesia, Relaxation was assessed 15 and 30 minutes before anesthesia using a standard questionnaire

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100518003954N9**
Registration date: **2020-02-14, 1398/11/25**
Registration timing: **retrospective**

Last update: **2020-02-14, 1398/11/25**
Update count: **0**

Registration date
2020-02-14, 1398/11/25

Registrant information

Name
Mohammad Hossein Bakhshaei

Name of organization / entity
Hamedan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-08-23, 1397/06/01

Expected recruitment end date

2019-08-23, 1398/06/01

Actual recruitment start date

2018-08-23, 1397/06/01

Actual recruitment end date

2019-08-23, 1398/06/01

Trial completion date

2019-08-23, 1398/06/01

Scientific title

Comparing the effect of intranasal ketamin and intranasal dexmedetomedin versus placebo on sedation,bleeding,pain & agitation in children undergoing adenotonsilectomy

Public title

The effect of ketamine and dexmedetomidine on preoperative sedation and intraoperative bleeding and analgesia during recovery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children undergoing adenotonsillectomy surgery who do not have concomitant disease.

Exclusion criteria:

Drug sensitivity to ketamine or dexmedothymidine Mental retardation ADHD Psychiatric drug use History of heart, kidney, liver disease Any pathological problems in the nose Patients who return to the operating room due to postoperative bleeding

Age

From **4 years** old to **12 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **3**

More than 1 sample in each individual

Number of samples in each individual: **3**

3 groups of A & B & c, each of which 31 patients were studied and a total of 93 patients were evaluated at the end

Actual sample size reached: **93**

Randomization (investigator's opinion)

Randomized

Randomization description

For this purpose we will use the hexadecimal random blocks method. For this purpose, we produce six sheets of paper. On the two sheets the letter K means "Ketamin" and on the other two sheets the letter D "dexmedetomedin" and on the two sheets the letter P means Placebo. Mix the sheets together and place in a drawer. On referral to each eligible patient, one leaf was randomly drawn and assigned to one of three study groups according to this leaflet, whether K, D or P. It should be noted that the drawn sheets will not be returned to the drawer until all six sheets have been drawn. After randomly pulling out all six sheets, all sheets will be returned to the drawer and the same operation will continue for the next six patients until the desired sample size (93 patients) is reached.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study, the researcher first presents the necessary explanations to the child's father {patient's father}. In the drawer she receives from the nurse, the patient is left unaware of the chosen group. Questionnaires and surveys are carried out by the researcher to the end. The analyzer analyzes the data based solely on the three types of groups a, b, and c, and after receiving the information from the analyzer, the nurse determines the relationship between the groups at the end.

Placebo

Used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamedan university of Medical sciences

Street address

Hamedan University of Medical Sciences

City

Hamedan

Province

Hamadan

Postal code

6515713834

Approval date

2018-07-09, 1397/04/18

Ethics committee reference number

IR.UMSHA.REC.1397.418

Health conditions studied

1

Description of health condition studied

Evaluation of the effect of ketamine or dexmedetomidine on placebo for preoperative relaxation& Intraoperative hemorrhage and postoperative analgesia in patients undergoing adenotonsillectomy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Relaxation before intranasal injection of ketamine or dexmedetomidine in adenotonsillectomy
Timepoint
Evaluation of sedation before adenotonsillectomy in children receiving intranasal ketamine or dexmedetomidine versus placebo 15 and 30 minutes after drug administration
Method of measurement
Questionnaire according to clinical criteria

Secondary outcomes

1

Description
Evaluation of the effect of medication on intraoperative bleeding
Timepoint
At the end of surgery.
Method of measurement
Calculation of bleeding inside the suction bottle and bleeding medical gases

2

Description
Evaluation of the effect of medication on postoperative pain and restlessness
Timepoint
Evaluation of patient pain and restlessness at 15, 30, 45 and 60 minutes after surgery in recovery
Method of measurement
Using the standard questionnaire: Children's Hospital of Eastern Ontario pain score and Pediatric Anesthesia Emergency Delirium (PAED) scal

Intervention groups

1

Description
Intervention group: This study is a randomized clinical trial of children in need of elective adenotonsillectomy with ASA status I and II in Hamadan Baysat Hospital in 1397. After sufficient explanation is given to parents if they consent to participate in the informed consent study. Patients were randomly divided into three groups: dexmedetomidine (D), ketamine (k) and placebo (normal saline (NS)). Patients were given 2µg / kg of dexmodetimidine or 5mg / kg of ketamine 30 minutes before induction of anesthesia and in the control group received 5 drops of 9% normal saline with 2mg syringe when the child was present with their parents.Medications are given in both nostrils in recumbent position. Blood pressure, pulse rate, and Spo2 were measured every 15 minutes until the patient was discharged from the recovery room. Patients were treated with 1mg / kg fentanyl intravenously and anesthetized with isoflurane 20 minutes prior to anesthesia. Completion of the procedure for all patients for analgesia is 15 mg / kg of acetaminophen infused with 20 cc normal saline. Intervention group 1: Intranasal ketamine 5 mg / kg once 30 min before anesthesia • Intervention group 2: Intranasal dexmedothymidine 2 micrograms per kg 30 minutes before anesthesia • Comparison group: Normal saline intravenously Nose 4 drops once 30 minutes before anesthesia begins
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat hospital
Full name of responsible person
Mohammadhossein Bakhshaei
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Deputy of research and technology
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Grant name
Hamadan University of Medical Sciences
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Hamedan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Individual data of study participants, after unidentifiable individuals, can be shared in most tables and graphs.
When the data will become available and for how long
Start data access period 6 month after printing results
To whom data/document is available
The data will be available to researchers working in academic and scientific institutions.
Under which criteria data/document could be used
It is possible to use the data after obtaining the written consent of the researchers
From where data/document is obtainable
Dr. Mohammad Hossein Bakhshai :

bakhshaei@umsha.ac.ir Dr. Mohsen Zarei : drm.zarei@yahoo.com

What processes are involved for a request to access data/document

If you send an email, the data request will be answered within a week.

Comments